

MAR - 9 2001

510(k) Summary**I. General Information on Submitter:**

Name: Apothecus Pharmaceutical Corp.
Address: 220 Townsend Square
Oyster Bay, NY 11771
Telephone: (516) 624-8200
Fax: (516) 624-8201
Name of Contact Person: Daniel Leon
Date Summary Prepared: October 11, 2000

II. General Information on Device

Name: VCF[®] Personal Lubricant

Classification Name: Accessory to a Condom

III. Predicate Devices:

Astroglide[®] Personal Lubricant (K935299)
CVS[®] Personal Lubricant (K983216)

IV. Description of the Device:

The device is a water based personal lubricant containing deionized water, glycerin USP, propylene glycol, polyquarternium-5, methylparaben, and propylparaben.

V. Intended Use:

The VCF[®] Personal Lubricant is indicated for personal lubrication, lubrication of a body orifice to facilitate entry of a diagnostic or therapeutic device, as a moisturizer for vaginal dryness, to enhance condom use, and to ease intimate activity.

VI. Technological Characteristics of Device Compared to Predicate Devices:

The technological characteristics of the VCF[®] Personal Lubricant are identical to those of the predicate devices.

VII. Summary of Performance Data

The VCF[®] Personal Lubricant was tested for condom compatibility, preservative effectiveness, and stability. For condom compatibility, condoms treated with the lubricant and exposed to physiological temperature were tested (physical properties and water leakage)

and the results were compared with the results obtained from the same tests conducted with control (water treated) condoms. Those test results did not indicate any clinically significant adverse effects associated with the use of the VCF[®] Personal Lubricant with latex condoms.

The preservative effectiveness testing was conducted in accordance with USP methods and demonstrated the effectiveness of the preservatives used in the product. Stability was demonstrated through preservative effectiveness testing conducted on samples subjected to accelerated stability conditions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Apothecus Pharmaceutical Corp.
c/o Gary L. Yingling, Esq.
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
WASHINGTON DC 20006-1108

Re: K010182
VCF® Personal Lubricant
Dated: January 19, 2001
Received: January 19, 2001
Regulatory Class: II
21 CFR §884.5300/Procode: 85 HIS
21 CFR §880.6375/Procode: 85 MMS

Dear Mr. Yingling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

David A. Segerson
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number: K010182

Device Name: VCF® Personal Lubricant

Indications for Use:

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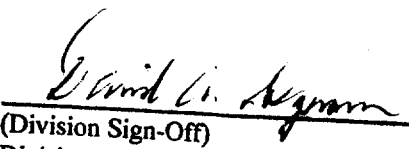
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010182